UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,211	06/18/2001	Robertson Scott Alan	PC10743A	3787

7590 06/03/2004

Paul H. Ginsburg
Pfizer Inc
20th Floor
235 East 42nd Street
New York, NY 10017-5755

EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,211	ALAN ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20,24,70 and 71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11 and 12* is/are allowed.

6)☐ Claim(s) *13-20, 24, 70, 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/01 and 1/4/2*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 3/2/04, have been entered in full. Applicant is reminded that the instant claims are being examined only to the extent that they relate to the species of SEQ ID NO: 2.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Information Disclosure Statement

In the prior Office action, the examiner informed Applicant the IDS of 10/29/01 was not present in the application. Apparently, however, the IDS and copies of all references have been found and are scanned in the application. A copy of the IDS, which has now been considered by the examiner, is attached. Applicant asserts that a copy of the IDS and copies of the references form 10/29/01 and April 1, 2002 have been newly provided, however there is no record of these newly provided documents in the file. The April 1, 2002 IDS was considered previously and a copy of this is provided to Applicant in this Office action.

Sequence Rules Compliance:

Applicant is notified that the application now appears to be in compliance with the requirements of 37 CFR 1.821 through 1.825.

Maintained Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims13-20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as set forth previously because the specification, while being enabling for polynucleotides encoding a polypeptide of SEQ ID NO: 3 or 4, and fragments thereof, and fragments thereof with additional heterologous sequences, e.g. epitope tags or carrier proteins, does not reasonably provide enablement polynucleotides encoding polypeptides *comprising* portions of SEQ ID NO: 3 or 4 or which need only hybridize to the encoding polynucleotide under the recited conditions or share a percent identity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims, for the reasons detailed previously.

Applicant argues that the claims have been amended to require that the recited sequence encode a "functional melanocortin-4 receptor". This argument has been fully considered but not deemed persuasive. Not withstanding the fact that the specification has not defined a "functional melanocortin-4 receptor", Applicant's argument is not persuasive because one of skill in the art

understands that simply writing down or verbalizing that a protein should have a certain function in no way enables the artisan to obtain such a protein.

Applicant argues that the specification has provided guidance as to how to obtain such sequences without undue experimentation. This argument has been fully considered but not deemed persuasive. The locations in the specification, pointed to by Applicant, simply recite generalize methodology that the artisan might use to try to find such sequences, however the skilled artisan understands that it is specific and not generalized information that is required, e.g. which positions can be substituted/added/deleted and which types of substitutions can be made at those positions. This information is completely lacking in the instant specification.

Claims 13-20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth previously.

Applicant argues that the scope of the genus has been adequately described by way of structural, e.g. percent identity, and functional features. This argument has been fully considered but not deemed persuasive. Regarding the structural description, that an unknown protein is to share some percent identity with a known protein imparts no specific information to the unknown protein. Percent identity is simply an average of the deviations between the two and provides absolutely no information as to any particular sequence or activity of the unknown protein. Further, one of skill in the art understands that simply writing down or verbalizing that a

protein should have a certain function in no way puts one in possession such a protein or a nucleic acid encoding the protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-20, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth previously.

The claims require a "functional MC4R", yet the specification does not set forth a definition of this term such that the artisan would unambiguously know whether he or she was in possession of a molecule meeting the limitations of the claim. Must a "functional MC4R" have each of the functions depicted in Figs 5-11, or only some? Perhaps a "functional MC4R" is only a small portion of the protein that is capable of eliciting an immune response, e.g. page 41. Thus, the artisan cannot be reasonably appraised of the metes and bounds of the claims because of the presence of this term.

Applicant argues that the term is clear in light of the specification at pages 15, 24, and 52-55. This argument has been fully considered but not deemed persuasive. The specification never defines the term. At page 15 the specification refers to "functionally equivalent MC4R" not a functional MC4R, The discussion at page 24 the specification begins with assertion that the following is "by way of example but not limitation". The example on pages 52-55 does not attempt to define the meaning of "functional MC4R".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-20, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No: 5622860, to Yamada et al, published April 22, 1997.

Yamada disclose an isolated polynucleotide encoding a human MC4R (SEQ ID NO: 8) that is 94% identical to the instant SEQ ID NO: 4, and 100% identical at positions 268-279 and 302-333 of SEQ ID NO: 4, see attached alignment. Vectors, host cells and methods of expression and functional assays are also disclosed, e.g. cols 14-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over No: 5622860, to Yamada et al.

Yamada disclose an isolated polynucleotide encoding a human MC4R (SEQ ID NO: 8) that is 94% identical to the instant SEQ ID NO: 4, and 100% identical at positions 268-279 and

302-333 of SEQ ID NO: 4, see attached alignment. The instant claims require polynucleotides that consist of polynucleotides encoding positions 268-279 and 302-333 of SEQ ID NO: 4. Yamada do not specifically state that polynucleotides consist of only these positions, yet the extracellular, transmembrane, and intracellular regions of GPCRs are well developed in the art and one of ordinary skill in the art would appreciate that positions 268-279 would be extracellular, and that the N-terminal positions 302-333 would be intracellular and that it would be desirous to make polynucleotides encoding only those positions so as to study the different physical properties of the receptor. If this is not the case, then claims 70 and 71 would be considered new matter, because the instant specification, as filed, does not make reference to the claimed polynucleotides.

Allowable Subject Matter

Claims 11 and 12 are allowed.

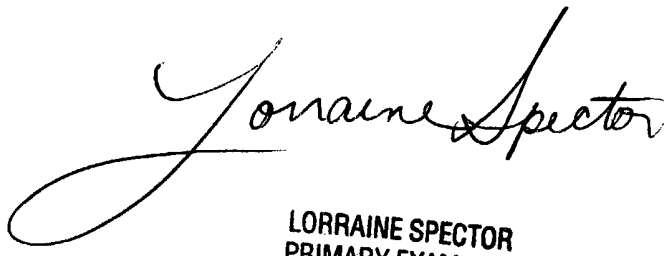
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached at (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



LORRAINE SPECTOR
PRIMARY EXAMINER

MB

May 28, 2004

Sequence alignment between 09884211-4 and U.S. Patent No: 5622860

```
XX
PN   US5622860-A.
XX
PD   22-APR-1997.
XX
PF   17-FEB-1994;   94US-00200711.
XX
PR   17-FEB-1994;   94US-00200711.
XX
PA   (UNMI ) UNIV MICHIGAN.
XX
PI   Gantz I,  Yamada T;
XX
DR   WPI; 1997-244394/22.
DR   N-PSDB; AAT68790.
XX
PT   Nucleic acid molecules encoding melanocortin receptors - useful to
PT   transfect mammalian cells lacking endogenous receptors to induce their
PT   expression.
XX
PS   Claim 4; Col 43-46; 58pp; English.
XX
CC   AAW19703-W19707 represent the human and mouse melanocortin (MC)
CC   receptors. This sequence represents the MC4R, expressed primarily in
CC   brain, but absent in the adrenal cortex, melanocytes and placenta. The
CC   gene encoding this sequence is located at chromosome locus 18q21.3. MCs
CC   are products of pro-opiomelanocortin post-translational processing, and
CC   are known to have a broad array of physiological actions. MCs are known
CC   to have effects on adrenal cortical functions and on melanocytes, as well
CC   as affecting behaviour, learning, memory, control of the cardiovascular
CC   system, analgesia, thermoregulation and the release of other neurohumoral
CC   agents (such as prolactin and biogenic amines). The nucleic acids can be
CC   used to transfect mammalian cells lacking endogenous MC receptors to
CC   induce their expression. These sequences can also be used to screen and
CC   identify drugs which specifically react with MCRs on the surface of a
CC   cell. The drugs can then be used for treating diseases which have MCRs
CC   implicated as one of their causes. Vectors containing these sequences can
CC   also be used to treat the diseases
XX
SQ   Sequence 332 AA;

  Query Match             94.9%;  Score 1638.5;  DB 2;  Length 332;
  Best Local Similarity   95.5%;  Pred. No. 1.3e-169;
  Matches  317;  Conservative    6;  Mismatches    8;  Indels    1;  Gaps    1;

Qy          1 MNSTLQHGMHTSLHFWNRSTYGQHGNATESLGKGYPDGGCYEQLFVSPEVFVTLGVISLL 60
              :|||   ||||||| |||||| | ||:||||||| |||||||||||||||||||||||
Db          2 VNST-HRGMHTSLHLWNRSSYRLHSNASESLGKGYSDGGCYEQLFVSPEVFVTLGVISLL 60

Qy         61 ENILVIVAIAKNKNLHSPMYFFICSLAVADMLVSVSNGSETIVITLLNSTDTDAQSFTVN 120
              ||||||||||||||||||||||||||||||||||||||||||:||||||||||||||||
Db         61 ENILVIVAIAKNKNLHSPMYFFICSLAVADMLVSVSNGSETIIITLLNSTDTDAQSFTVN 120

Qy        121 IDNVIDSVICSSLLASICSLLSIAVDRYFTIFYALQYHNIMTVRRVGIIISCIWAACTVS 180
              |||||||||||||||||||||||||||||||||||||||||||:||||||||||||||||
Db        121 IDNVIDSVICSSLLASICSLLSIAVDRYFTIFYALQYHNIMTVKRVGIIISCIWAACTVS 180

Qy        181 GILFIIYSDSTAVIICLITMFFTMLALMASLYVHMFLMARLHIKRIAVLPGTGTIRQGAN 240
              ||||||||||:|||||||||||||||||||||||||||||||||||||| ||||||
Db        181 GILFIIYSDSSAVIICLITMFFTMLALMASLYVHMFLMARLHIKRIAVLPGTGAIRQGAN 240

Qy        241 MKGAITLTILIGVFVVCWAPFFLHLIFYISCPQNPYCVCFMSHFNLYLILIMCNSIIDPL 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 MKGAITLTILIGVFVVCWAPFFLHLIFYISCPQNPYCVCFMSHFNLYLILIMCNSIIDPL 300

Qy        301 IYALRSQELRKTFKEIICCYPLGGLCDLSSRY 332
              ||||||||||||||||||||||||||||||||
Db        301 IYALRSQELRKTFKEIICCYPLGGLCDLSSRY 332


RESULT 4
AAW33724
ID   AAW33724 standard; protein; 332 AA.
```